

# PATENT COOPERATION TREATY

REC'D 21 MAR 2005

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From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

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## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 17-03-2005

Applicant's or agent's file reference

AH53722

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

PCT/SE 2004/001879

International filing date (day/month/year)

15.12.2004

Priority date (day/month/year)

15.12.2003

International Patent Classification (IPC) or both national classification and IPC

A61M 25/10, A61M 16/04, A61L 2/16

Applicant

Nitricare KB et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/SE

Patent- och registreringsverket

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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/SE 2004/001879

**Box No. I      Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 18-39, 51-53

because:

- ☒ the said international application, or the said claims Nos. 18-39, 51-53  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ The claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- the written form ☐ has not been furnished  
☐ does not comply with the standard
- the computer readable form ☐ has not been furnished  
☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

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**Box No. V    Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	<u>1-17, 40-50</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-17, 40-50</u>	NO
Industrial applicability (IA)	Claims	<u>1-17, 40-50</u>	YES
	Claims		NO

**2. Citations and explanations:**

The following documents are cited in the International Search Report:

D1: US 5417657 A1

D2: S. Carlsson, N.P. Wiklund, L. Engstrand, E. Weitzberg, J.O.N. Lundberg, "Effect of pH, Nitrite and Ascorbic Acid on Nonenzymatic Nitric Oxide Generation and Bacterial Growth in Urine", NITRIC OXIDE: Biology and Chemistry, Vol. 5, No. 6, (2001), pp. 580-586

D3: WO 8401721 A1

The present application pertains to a device and a method for reducing the risk of infections acquired during hospital treatment, so called nosocomial infections, which arise after the insertion of catheters, intratracheal tubes and similar devices into a human or animal body. The device has an expandable part to keep it in place and releases at least one low molecular antimicrobial compound (LMAC) which penetrates through the device and exerts antimicrobial action on the surroundings.

D1 (column 3 line 5-22, column 4 line 31-49, claim 1) describes a urinary catheter comprising a microporous balloon which releases drugs to kill and prevent bacterial growth in and around the urinary bladder.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D1 is considered to be the document which represents the closest prior art. Claims 1-6, 9-16, 40, 41 and 44-49 differ from D1 in that a low molecular drug, i.e. a low molecular antimicrobial compound (LMAC), is used as the drug. The LMAC may be reactive nitrogen- or oxygen intermediates. The LMAC may be released by nitrite in an acidic or basic environment and ascorbic acid may be used in combination with nitrite.

The problem solved by the present invention is therefore considered as finding compounds that are reactive nitrogen- or oxygen intermediates. The compound may be released by nitrite in an acidic environment where the reactive nitrogen- or oxygen intermediates have antimicrobial action.

D2 describes an investigation concerning the effect of pH, nitrite and ascorbic acid on bacterial growth in urine (see abstract). According to D2, it is possible to release reactive nitrogen intermediates by acidifying urine containing nitrite, see page 582, column 2 lines 1-22.

What is described in document D2 is considered as having the same advantages as the present application. It is thus considered obvious to the person skilled in the art to include this "part" in the device which is described in document D1 to solve the present problem. The invention according to claims 1-6, 9-16, 40, 41 and 44-49 is thus considered to lack inventive step.

Claims 7, 8, 42 and 43 differ from D1 and D2 in that devices other than catheters, which can be inserted into the body are mentioned. The description in the present application only has examples comprising catheters. It is considered as obvious to the person skilled in the art to adapt what is known from D1 and D2 for use in other devices which are inserted into the body. The invention according to claims 7, 8, 42 and 43 is thus considered to lack inventive step.

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**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**

Continuation of: Box V

The invention according to claim 17 differs from D1 and D2 because metal ions are present in the device for insertion into the body. The metal ions contribute to increasing the antimicrobial effect. In claim 50 zinc is used in combination with nitrite and ascorbic acid.

D3 describes a method where zinc is known to be used as an antimicrobial metal in catheters, see abstract and page 4. It is considered as obvious to the person skilled in the art to use what is known from D3 to attain the invention according to claims 17 and 50. The invention according to claims 17 and 50 thus lacks inventive step.